



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0125]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection aspects of the Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007.

DATES: Submit either electronic or written comments on the collection of information by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received by mail/hand

delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2011-D-0125 for “Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry on Establishing That a Tobacco Product Was Commercially Marketed in

the United States as of February 15, 2007

OMB Control Number 0910-0775--Extension

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111-31) was signed into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding, among other things, a chapter granting FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)), as amended, defines a tobacco product as any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product). Section 910 of the FD&C Act (21 U.S.C. 387j) sets out premarket requirements for new tobacco products. The term new tobacco product is defined as any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007, or any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery, or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007 (section 910(a)(1) of the FD&C Act).

The Tobacco Control Act also gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product to be subject to chapter IX of the FD&C Act (section 901(b) (21 U.S.C. 387a(b)) of the FD&C Act). On May 10, 2016, FDA issued that rule, extending FDA's tobacco product authority to all products that meet the definition of tobacco product in the law (except for accessories of newly regulated tobacco products), including electronic nicotine delivery systems, cigars, hookah, pipe tobacco, nicotine gels, and dissolvables that were not already subject to the FD&C Act, and other tobacco products that may be developed in the future (81 FR 28974 at 28976).

FDA refers to tobacco products that were commercially marketed (including those products in test markets) in the United States as of February 15, 2007, as Pre-Existing tobacco

products.¹ Pre-Existing tobacco products are not considered new tobacco products and are not subject to the premarket requirements of section 910 of the FD&C Act. The guidance document associated with this information collection entitled “Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2007

(<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/establishing-tobacco-product-was-commercially-marketed-united-states-february-15-2007>), provides information on how a manufacturer may establish that a tobacco product was commercially marketed in the United States as of February 15, 2007. A Pre-Existing tobacco product (except such products exclusively in test markets) may also serve as the predicate tobacco product in a section 905(j) report (intended to be used toward demonstrating substantial equivalence) for a new tobacco product (section 905(j)(1)(A)(i) of the FD&C Act (21 U.S.C. 387e(j)(1)(A)(i))).

The guidance recommends that the manufacturer submit information adequate to demonstrate that the tobacco product was commercially marketed in the United States as of February 15, 2007. Examples of such information may include, but are not limited to, the following: dated copies of advertisements, dated catalog pages, dated promotional material, and dated bills of lading.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Submit evidence of commercial marketing in the United States as of February 15, 2007	1,000	1	1,000	5	5,000

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

¹ FDA changed the term from “grandfathered tobacco product” to “Pre-Existing tobacco product” in the recently published final SE (86 FR 55224) and PMTA (86 FR 55300) rules because it more appropriately describes these products by using the more precise “Pre-Existing” in place of “grandfathered.”

FDA's estimate of the number of respondents is based on the fact that requesting an Agency determination of the Pre-Existing status of a tobacco product under the guidance is not required and also on the number of Pre-Existing tobacco product submissions received from 2011 to October 2021. For deemed products that met the definition of a new tobacco product and were on the market as of August 8, 2016 (when the deeming rule took effect), FDA issued a compliance policy; this, in effect, provided more time for manufacturers of these products to submit their applications for marketing authorization. The deadline for the submission of applications for these products has now passed. As the result of a court order (and a subsequent extension due to the unique circumstances of the COVID-19 pandemic), applications for deemed new tobacco products on the market at that time were due to FDA by September 9, 2020.² The court order also provided a 1-year period during which products with timely filed applications might remain on the market pending FDA review. The number of hours to gather the evidence is FDA's estimate of how long it might take a manufacturer to review, gather, and submit dated information if making a request for Agency determination.

FDA further estimates it would take a manufacturer approximately 5 hours to put together this collection of evidence and to submit the package to FDA for review. FDA estimates that it would take approximately 5,000 hours annually to respond to this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

² On August 19, 2020, the U.S. District Court for the District of Columbia issued a ruling, in part, to prohibit FDA enforcement of the Tobacco Control Act's premarket authorization requirement for premium cigars until after the agency considers developing a streamlined substantial equivalence process specifically for premium cigars. Accordingly, FDA will not enforce the premarket review requirement against manufacturers of premium cigars that do not submit premarket applications for these products by the September 9, 2020 deadline.

Dated: December 2, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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